Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Clinical practice guideline: evaluation of the neck mass in adults.

Bibliographic Source(s)

Pynnonen MA, Gillespie MB, Roman B, Rosenfeld RM, Tunkel DE, Bontempo L, Brook I, Chick DA, Colandrea M, Finestone SA, Fowler JC, Griffith CC, Henson Z, Levine C, Mehta V, Salama A, Scharpf J, Shatzkes DR, Stern WB, Youngerman JS, Corrigan MD. Clinical practice guideline: evaluation of the neck mass in adults. Otolaryngol Head Neck Surg. 2017 Sep;157(2_suppl):S1-S30. [117 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
YES	Multidisciplinary Group

YES	Methodologist Involvement
▮▮▮▮▮	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▮▯	Study Selection
▮▮▮▯▯	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▯	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▮	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▮▮▯	External Review
▮▮▮▮▮	Updating

Recommendations

Major Recommendations

The evidence grades (A-D, X) and evidence-based statements (Strong Recommendation, Recommendation, and Option) are defined at the end of the "Major Recommendations" field.

Statement 1. Avoidance of Antibiotic Therapy

Clinicians should not routinely prescribe antibiotic therapy for patients with a neck mass unless there are signs and symptoms of bacterial infection.

Recommendation based on observational studies with a preponderance of benefits over harm.

Action Statement Profile

Quality improvement opportunity: Avoid routine treatment with antibiotics, which may be inappropriate or ineffective treatment for a neck mass, thus leading to delayed diagnosis of malignancy or other serious illness. (National Quality Strategy domains: safety, promoting effective treatment, affordable quality care)
Aggregate evidence quality: Grade C, based on observational studies
Level of confidence in evidence: Medium
Benefits: Avoid delay in diagnosis of malignancy, promote judicious antibiotic therapy, limit bacterial resistance, reduce antibiotic adverse effects, reduced cost
Risks, harms, costs: Under treatment of a missed bacterial infection

Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: Perception by the guideline development group (GDG) that antibiotics are common for noninfectious neck masses, delaying diagnosis and/or referral. Further perception that physical examination is the primary determinant of an infectious cause of a neck mass, and history is a secondary determinant.
Intentional vagueness: None
Role of patient preferences: None
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 2a. Stand-Alone Suspicious History

Clinicians should identify patients with a neck mass who are at increased risk for malignancy when the patient lacks a history of infectious etiology and the mass has been present for ≥2 weeks without significant fluctuation or the mass is of uncertain duration.

Recommendation based on observational studies with a preponderance of benefits over harm.

Action Statement Profile

Quality improvement opportunity: To use simple questions to identify patients at increased risk for malignancy based on specific historical features. (National Quality Strategy domains: safety, promoting effective prevention/treatment)
Aggregate evidence quality: Grade C, based on observational studies
Level of confidence in evidence: Medium
Benefits: Improve outcomes through earlier diagnosis, identify patients with an earlier stage of disease, prioritize testing for high-risk patients, potentially reduce risk of distant metastases through earlier cancer identification, provide psychological benefit through timely evaluation, facilitate further care
Risks, harms, costs: False-positive clinical diagnosis resulting in subsequent tests and anxiety in patients with nonmalignant disease
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: The risk of missing or delaying diagnosis of a malignancy in a patient who is at increased risk is more important than false-positive clinical diagnosis in a patient with nonmalignant disease. Assumption by the GDG that early identification of patients at increased risk with focused questions can improve outcomes, despite any direct clinical evidence to substantiate this assumption.
Intentional vagueness: None
Role of patient preferences: None
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 2b. Stand-Alone Suspicious Physical Examination

Clinicians should identify patients with a neck mass who are at increased risk for malignancy based on ≥1 of these physical examination characteristics: fixation to adjacent tissues, firm consistency, size >1.5 cm, and/or ulceration of overlying skin.

Recommendation based on observational studies with a preponderance of benefits over harm.

Action Statement Profile

Quality improvement opportunity: To identify patients at increased risk for malignancy because of specific features on physical examination. (National Quality Strategy domains: safety, promoting effective prevention/treatment)
Aggregate evidence quality: Grade C, based on observational studies

Level of confidence in evidence: Medium
Benefits: Improve outcomes through earlier diagnosis, identify patients with earlier stage of disease, prioritize testing for patients at increased risk, potentially reduce risk of distant metastases through earlier cancer identification, psychological benefit of timely evaluation, facilitate further care
Risks, harms, costs: False-positive clinical diagnosis resulting in subsequent tests and anxiety in patients with nonmalignant disease
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: The risk of missed or delayed diagnosis of malignancy is more important than the risk of a false-positive clinical diagnosis. Despite any direct clinical evidence, the GDG assumed that early identification of patients at increased risk of malignancy may improve outcomes.
Intentional vagueness: None
Role of patient preferences: None
Exceptions: None
Policy level: Recommendation
Differences of opinion: GDG debated whether firm consistency of the mass is a predictor of malignancy (majority opinion: 14 of 18 felt that firmness is predictive of malignancy); GDG also debated whether absolute size of the mass, regardless of neck location, is a predictor of malignancy.

Statement 2c. Additional Suspicious Signs and Symptoms

Clinicians should conduct an initial history and physical examination for all adults with a neck mass to identify those patients with an increased risk for malignancy.

Recommendation based on observational studies with a preponderance of benefits over harm.

Action Statement Profile

Quality improvement opportunity: This statement moves beyond the previously noted stand-alone suspicious findings (lack of infectious etiology, ≥2-week duration of the mass, reduced mobility, firm texture, size >1.5 cm, ulceration) by using the initial history and examination to identify patients who have signs and symptoms that place them at increased risk of malignancy. (National Quality Strategy domains: safety, promoting effective prevention/treatments)
Aggregate evidence quality: Grade C, based on case series
Level of confidence in evidence: Medium
Benefits: Improve outcomes through earlier diagnosis, identify patients with earlier stage of disease, prioritize testing for increased-risk patients, potentially reduce risk of distant metastases through earlier cancer identification, psychological benefit of timely evaluation, facilitate further care
Risks, harms, costs: False-positive clinical diagnosis resulting in subsequent tests and anxiety in patients with nonmalignant disease
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: The risk of missing or delaying diagnosis of malignancy in an increased-risk patient is more important than potentially misclassifying patients with nonmalignant disease. Assumption by the GDG that early identification of at-risk status with the initial history and physical examination can improve outcomes. Assumption by the GDG that the listed signs and symptoms can predict risk of cancer above and beyond lack of infectious etiology, ≥2 weeks' duration of mass, reduced mobility, firm texture, size >1.5 cm, ulceration.
Intentional vagueness: None
Role of patient preferences: None
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 3. Follow-up of the Patient Not at Increased Risk

For patients with a neck mass who are not at increased risk for malignancy, clinicians or their designees should advise patients of criteria that would trigger the need for additional evaluation. Clinicians or their designees should also document a plan for follow-up to assess resolution or final diagnosis.

Recommendation based on observational studies with a preponderance of benefits over harm.

Action Statement Profile

Quality improvement opportunity: Promote follow-up and engage patients in their care for better outcomes. (National Quality Strategy domains: engaging patients, effective prevention/treatment)
Aggregate evidence quality: Grade C
Level of confidence in evidence: Medium
Benefits: Avoid false-negative diagnosis based on initial assessment, promote follow-up to ensure resolution of benign lesions and detect malignant masses, promote more timely diagnosis if the mass fails to resolve as expected, educate and empower patients, and promote shared decision making.
Risks, harms, costs: Administrative burden for the clinician, health care cost of follow-up assessments
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: Perception by the GDG that patients with neck masses receive inconsistent follow-up, despite its importance
Intentional vagueness: The timing and method of follow-up are not specified
Role of patient preferences: Moderate regarding the method of follow-up
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 4. Patient Education

For patients with a neck mass who are deemed at increased risk for malignancy, clinicians or their designees should explain to the patient the significance of being at increased risk and explain any recommended diagnostic tests.

Recommendation based on observational studies with preponderance of benefits over harms.

Action Statement Profile

Quality improvement opportunity: (National Quality Strategy domains: safety, effective treatment)
Aggregate evidence quality: Grade C, observational studies of the utility of diagnostic tests and imaging studies to assist with diagnosis of neck mass
Level of confidence in evidence: Medium
Benefits: Improve understanding of the risk of malignancy in a neck mass, as well as understanding of the need for targeted examination and tests/imaging, engage patients, establish expectations
Risks, harms, costs: None
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: None
Intentional vagueness: None
Role of patient preferences: None
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 5. Targeted Physical Examination

Clinicians should perform, or refer the patient to a clinician who can perform, a targeted physical examination (including visualizing the mucosa of the larynx, base of tongue, and pharynx), for patients with a neck mass deemed at increased risk for malignancy.

Recommendation based on grade C aggregate evidence (observational studies) with a preponderance of benefit over harm.

Action Statement Profile

Quality improvement opportunity: To encourage the use of a complete examination of the neck and the mucosal surfaces of the aerodigestive tract. (National Quality Strategy domains: safety, effective treatment)
Aggregate evidence quality: Grade C observational studies
Level of confidence in evidence: High
Benefits: Identification of a primary source of neck mass or malignancy, focus and prioritize subsequent diagnostic tests, ensure that the patient has a full examination of mucosal surfaces by someone with the necessary diagnostic skills and/or equipment
Risks, harms, costs: Cost of visit, cost and risks of diagnostic tests, detection of incidental lesions, false-positive diagnosis, discomfort (e.g., laryngoscopy)
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: Consensus by the GDG that imaging is not a substitute for the additional information obtained by an examination that includes complete examination of the mucosal surfaces
Intentional vagueness: The method (mirror or endoscope) of examination is at the discretion of the clinician, as is the decision to refer the patient to another clinician if one is unable to visualize the pharynx, base of tongue, and larynx.
Role of patient preferences: Small to none; patient may decline examination
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 6: Imaging

Clinicians should order a neck computed tomography (CT) (or magnetic resonance imaging [MRI]) with contrast for patients with a neck mass deemed at increased risk for malignancy.

Strong recommendation based on randomized controlled trials.

Action Statement Profile

Quality improvement opportunity: To promote timely and effective imaging assessment of a neck mass in patients deemed at risk for malignancy
Aggregate evidence quality: Grade B, randomized controlled trials, consistent evidence from observational studies
Level of confidence in evidence: High
Benefits: Ensure that when imaging is ordered, the right test is selected and contrast is given, distinguish malignant from benign masses, plan for fine-needle aspiration (FNA) or biopsy, define extent of disease to facilitate staging, detect occult disease, guide treatment decisions, further testing and referral
Risks, harms, costs: Radiation (CT), contrast adverse reactions, anxiety, claustrophobia, cost, incidental findings, false positives, false negatives
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: None
Intentional vagueness: The clinician may choose whether to order CT or MRI based on the specific clinical situation.
Role of patient preferences: Small role. Claustrophobic patients may prefer CT over MRI. MRI may be preferable if radiation exposure is a concern.
Exceptions: Imaging recommendations may be altered in pregnancy. The protocol for contrast administration may be altered in the setting of contrast allergy or renal insufficiency.
Policy level: Strong recommendation
Differences of opinion: None

Statement 7. Fine-Needle Aspiration

Clinicians should perform FNA instead of open biopsy, or refer the patient to someone who can perform FNA, for patients with a neck mass deemed at increased risk for malignancy when the diagnosis of the neck mass remains uncertain.

Strong recommendation based on systematic reviews with a consistent reference standard.

Action Statement Profile

Quality improvement opportunity: Avoid unnecessary open biopsy with its associated complications and promote timely FNA as the initial pathologic test for a patient with a neck mass at increased risk of malignancy (National Quality Strategy domains: safety, effective treatment)
Aggregate evidence quality: Grade A, systematic reviews with a consistent reference standard
Level of confidence in evidence: High
Benefits: Rapid, cost-effective test with high sensitivity and specificity for diagnosis, minimal discomfort, low risk of seeding malignancy, does not affect imaging results, can prioritize further imaging or workup
Risks, harms, costs: Discomfort, direct cost, risk of nondiagnostic or indeterminate test results
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: Perception by the GDG that some patients undergo inappropriate open biopsy prior to attempted FNA. The GDG also noted that some patients experience unwarranted delay prior to tissue biopsy
Intentional vagueness: There are a variety of techniques, operators, and settings in which neck mass FNA may be performed; these choices are left to the discretion of the clinician and patient.
Role of patient preferences: None
Exceptions: None
Policy level: Strong recommendation
Differences of opinion: None

Statement 8. Cystic Masses

For patients with a neck mass deemed at increased risk for malignancy, clinicians should continue evaluation of patients with a cystic neck mass, as determined by FNA or imaging studies, until a diagnosis is obtained and should not assume that the mass is benign.

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

Quality improvement opportunity: Avoid misdiagnosis of malignant lesions with potentially decreased survival (National Quality Strategy domains: safety, effective treatment)
Aggregate evidence quality: Grade C
Level of confidence in evidence: High
Benefits: Avoid misdiagnosis of malignant lesions, avoid inappropriate care (e.g., excision, open biopsy), avoid delays in diagnosis, reduce false sense of security
Risks, harms, costs: Cost of additional diagnostic tests
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: Concern by the GDG that some patients receive false reassurance that a cystic mass is not of concern despite studies showing a high rate of malignancy and false-negative biopsies in such masses
Intentional vagueness: None
Role of patient preferences: None
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 9. Ancillary Tests

Clinicians should obtain additional ancillary tests based on the patient's history and physical examination when a patient with a neck mass is at increased risk for malignancy and/or does not have a diagnosis after FNA and imaging.

Recommendation based on nonconsecutive studies, observational studies, case series, and panel

consensus with preponderance of benefit over harm.

Action Statement Profile

Quality improvement opportunity: To identify laboratory or other test that can aid in neck mass diagnosis (National Quality Strategy domains: promoting effective prevention/treatment)
Aggregate evidence quality: Grade C, nonconsecutive studies, case-control studies, observational studies, case series
Level of confidence in evidence: Medium
Benefits: Diagnose neck mass and avoid invasive procedures/anesthesia
Risks, harms, costs: Direct costs of ancillary tests, false-positive tests, incidental findings, risk of failure to diagnose concurrent malignancy based on these test results
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: None
Intentional vagueness: The specific tests and timing are at the discretion of the clinician
Role of patient preferences: None
Exceptions: None
Policy level: Recommendation
Differences of opinion: None

Statement 10. Examination Under Anesthesia of the Upper Aerodigestive Tract Before Open Biopsy

Clinicians should recommend examination of the upper aerodigestive tract under anesthesia, before open biopsy, for patients with a neck mass who are at increased risk for malignancy and without a diagnosis or primary site identified with FNA, imaging, and/or ancillary tests.

Recommendation based observational studies with a preponderance of benefit over harm.

Action Statement Profile

Quality improvement opportunity: To improve understanding that a neck mass may be a metastatic lesion from a primary aerodigestive site and that identification of these lesions improves treatment outcomes (National Quality Strategy domains: safety, effective treatment)
Aggregate evidence quality: Grade C, observational studies
Level of confidence in evidence: High
Benefits: Potentially identify a primary site of cancer or rule out malignancy, obtain tissue for diagnosis
Risks, harms, costs: Direct costs of procedures, adverse effects of anesthesia, dental injury, cranial nerve injury, rare complications of endoscopy (bleeding, infection, perforation, airway obstruction)
Benefit-harm assessment: Preponderance of benefit over harm
Value judgments: Perception that some clinicians may be performing open biopsy of the neck before or without endoscopy during the same trip to the operating room and that endoscopy should preferably be performed prior to open biopsy
Intentional vagueness: The decision to perform open biopsy is at the discretion of the clinician (after FNA has been performed and is not diagnostic) but is usually performed after the endoscopy if the endoscopy does not reveal a primary site and if a high suspicion for malignancy remains
Role of patient preferences: Small. May decline intervention.
Exceptions: Patients who are at increased risk of procedure (anesthesia)
Policy level: Recommendation
Differences of opinion: Within the GDG, there were differences of opinion about whether the surgeon should be prepared to do a neck dissection at the same time as an open biopsy and frozen section

Definitions

Aggregate Grades of Evidence by Question Type[a]

Grade	CEBM Level	Treatment	Harm	Diagnosis	Prognosis
A	1	Systematic review[b] of randomized trials	Systematic review[b] of randomized trials, nested case-control studies, or observational studies with dramatic effect	Systematic review[b] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[b] of inception cohort studies[c]
B	2	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies[c]
C	3-4	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonrandomized controlled cohort or follow-up study (postmarketing surveillance) with sufficient numbers to rule out a common harm; case series, case-control, or historically controlled studies	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor-quality prognostic cohort study
D	5	Case reports, mechanism-based reasoning, or reasoning from first principles			
X	N/A	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm			

Abbreviation: CEBM, Oxford Centre for Evidence-Based Medicine; N/A, not applicable

[a]Adapted from Howick J, Chalmers I, Glasziou; the OCEBM Levels of Evidence Working Group. The Oxford 2011 levels of evidence: Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653 . Accessed October 22, 2015.

[b]A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

[c]A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Strength of Action Terms in Guideline Statements and Implied Levels of Obligation

Strength	Definition	Implied Obligation
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (grade A or B). In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of evidence is not as high (grade B or C). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive or patient preferences.
Option	An option means that either the quality of evidence is suspect (grade D) or that well-done studies (grade A, B, or C) show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although

Strength	Definition	Implied Obligation
		they may set bounds on alternatives; patient preference should have a substantial influencing role.

Clinical Algorithm(s)

An algorithm titled "Algorithm depicting the relationship among the key action statements (KASs)" is provided in the original guideline document.

Scope

Disease/Condition(s)

Neck mass

Note: A neck mass is defined as an abnormal lesion (congenital or acquired) that is visible, palpable, or seen on an imaging study. The Guideline Development Group (GDG) further qualified neck masses as any mass below the mandible, above the clavicle, and deep to the skin, although it may involve the overlying skin secondarily.

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Family Practice

Oncology

Otolaryngology

Intended Users

Dentists

Physicians

Guideline Objective(s)

- To promote the efficient, effective, and accurate diagnostic workup of neck masses to ensure that adults with potentially malignant disease receive prompt diagnosis and intervention to optimize outcomes
- To craft a set of actionable statements relevant to diagnostic decisions made by a clinician in the workup of an adult patient with a neck mass

Target Population

Patients ≥18 years old with a neck mass

Interventions and Practices Considered

1. Avoidance of antibiotic therapy
2. Stand-alone suspicious history
3. Stand-alone suspicious physical examination
4. Investigation of additional suspicious signs and symptoms for those at increased risk
5. Follow-up of the patient not at increased risk
6. Patient education, counseling, and shared decision making including explanation of increased risk, risk factors and recommended diagnostic tests
7. Targeted physical examination (including visualizing the mucosa of the larynx, base of tongue, and pharynx)
8. Computed tomography (CT) or magnetic resonance imaging (MRI) of the neck, with contrast
9. Fine-needle aspiration (FNA)
10. Continued evaluation until diagnosis is obtained for patients with cystic mass
11. Ancillary tests
12. Examination of the upper aerodigestive tract under anesthesia

Note: The following was considered but not recommended: routinely prescribing antibiotic therapy (unless there is evidence of a bacterial infection).

Major Outcomes Considered

- Diagnostic accuracy of tests
- Earlier diagnosis of head and neck squamous cell carcinoma (HNSCC)
- Identification of patients with an earlier stage of disease
- Reduction of risk of distant metastases
- Psychological benefit
- Quality of life
- Morbidity
- Mortality

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

The recommendations in this clinical practice guideline are based on systematic reviews identified by a professional information specialist using an explicit search strategy. Additional background evidence included randomized controlled trials and observational studies, as needed, to supplement the systematic reviews or to fill gaps when a review was not available. An information specialist conducted 2 systematic literature searches from December 2015 through February 2016 using a validated filter strategy to identify clinical practice guidelines, systematic reviews, randomized controlled trials, and comparative studies. For a complete list of search terms, refer to the original guideline document.

The English-language searches were performed in multiple databases, including PubMed (MEDLINE), EMBASE, CINAHL, Cochrane Library, National Guideline Clearinghouse, National Institute for Health and Care Excellence (NICE) UK, and Canadian Medical Association (CMA) Infobase (Canada). In certain instances, targeted searches for lower-level evidence were performed to address gaps from the

systematic searches identified in writing the guideline from April 2016 through November 2016. January 1980 was the beginning date for all of the searches.

Number of Source Documents

1. The initial search for clinical practice guidelines identified 11 guidelines. After removal of duplicates and irrelevant references, the total was 6 guidelines. Quality criteria for including guidelines were (a) an explicit scope and purpose, (b) multidisciplinary stakeholder involvement, (c) systematic literature review, (d) explicit system for ranking evidence, and (e) explicit system for linking evidence to recommendations. The final data set retained 3 guidelines that met inclusion criteria.
2. The initial search for systematic reviews identified 103 systematic reviews or meta-analyses. After removal of duplicates and irrelevant references, the total was 27 articles. Quality criteria for including reviews were (a) relevance to the guideline topic, (b) clear objective and methodology, (c) explicit search strategy, and (d) valid data extraction methods. The final data set retained was 10 systematic reviews or meta-analyses that met inclusion criteria.
3. The initial search for randomized controlled trials identified 20 trials. After removal of duplicates and irrelevant references, the total was 14 articles. Quality criteria for including randomized controlled trials were (a) relevance to the guideline topic, (b) publication in a peer-reviewed journal, and (c) clear methodology with randomized allocation to treatment groups. The total final data set retained 6 randomized controlled trials that met inclusion criteria.
4. The initial search for comparative studies identified 143 studies. After removal of duplicates and irrelevant references, the total was 140 articles. The quality criterion for including comparative studies was relevance to the guideline topic. The total final data set retained 51 comparative studies that met inclusion criteria.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Aggregate Grades of Evidence by Question Type[a]

Grade	CEBM Level	Treatment	Harm	Diagnosis	Prognosis
A	1	Systematic review[b] of randomized trials	Systematic review[b] of randomized trials, nested case-control studies, or observational studies with dramatic effect	Systematic review[b] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[b] of inception cohort studies[c]
B	2	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies[c]
C	3-4	Nonrandomized or historically controlled studies, including case-	Nonrandomized controlled cohort or follow-up study (postmarketing surveillance) with sufficient numbers to rule out a	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent,	Cohort study, control arm of a randomized trial, case series, or case-control

Grade	CEBM Level	Treatment	Harm	Diagnosis	Prognosis
		control and observational studies	common harm; case series, case-control, or historically controlled studies	or inconsistently applied reference standards	studies; poor-quality prognostic cohort study
D	5	Case reports, mechanism-based reasoning, or reasoning from first principles			
X	N/A	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm			

Abbreviation: CEBM, Oxford Centre for Evidence-Based Medicine; N/A, not applicable

[a]Adapted from Howick J, Chalmers I, Glasziou; the OCEBM Levels of Evidence Working Group. The Oxford 2011 levels of evidence: Oxford Centre for Evidence-Based Medicine. http://www.cebm.net/index.aspx?o=5653 . Accessed October 22, 2015.

[b]A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

[c]A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the *quality of evidence* and the *balance of benefit and harm* that is anticipated when the statement is followed. The definitions for evidence-based statements are listed in the "Rating Scheme for the Strength of Evidence" and "Rating Scheme for the Strength of the Recommendations" fields.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline was developed with an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm as outlined in the third edition of the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) guideline development manual. The guideline development group (GDG) consisted of 21 panel members representing experts in advanced practice nursing, clinical pathology, consumer advocacy, emergency medicine, general practice medicine, general surgery, head and neck surgery and oncology, otolaryngology, oral and maxillofacial surgery, physician assistants, and radiology.

In a series of conference calls, the GDG defined the scope and objectives of the proposed guideline. During the 12 months devoted to guideline development ending in August 2016, the GDG met twice, with in-person meetings following the format previously described, with use of decision support software (BRIDGE-Wiz; Yale Center for Medical Informatics, New Haven, Connecticut) to facilitate the creation of actionable recommendations and evidence profiles. Internal electronic review and feedback on each guideline draft were used to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines (CPGs).

The AAO-HNSF staff used the Guideline Implementability Appraisal and Extractor to appraise adherence of

the draft guideline to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Guideline panel members received summary appraisals in September 2016 and modified an advanced draft of the guideline.

Rating Scheme for the Strength of the Recommendations

Strength of Action Terms in Guideline Statements and Implied Levels of Obligation

Strength	Definition	Implied Obligation
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (grade A or B).[a] In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of evidence is not as high (grade B or C).[a] In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive or patient preferences.
Option	An option means that either the quality of evidence is suspect (grade D)[a] or that well-done studies (grade A, B, or C)[a] show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

[a]See the "Rating Scheme for the Strength of Evidence" field for definitions of evidence grades.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) staff used the Guideline Implementability Appraisal and Extractor to appraise adherence of the draft guideline to methodological standards, to improve clarity of recommendations, and to predict potential obstacles to implementation. Guideline panel members received summary appraisals in September 2016 and modified an advanced draft of the guideline.

The final guideline draft underwent extensive external peer review, including a period for open public comment. All comments received were compiled and reviewed by the panel's chair, and a modified version of the guideline was distributed and approved by the guideline development group (GDG). A scheduled review process will occur at 5 years from publication or sooner if new compelling evidence warrants earlier consideration.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Prompt diagnosis and intervention to optimize patient outcomes
- Reducing delays in diagnosis of head and neck squamous cell carcinoma (HNSCC)
- Appropriate testing, including imaging, pathologic evaluation, and empiric medical therapies
- Reducing inappropriate testing
- Appropriate physical examination when cancer is suspected

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

- Under treatment of a missed bacterial infection
- False-positive clinical diagnosis resulting in subsequent tests and anxiety in patients with nonmalignant disease
- Discomfort (e.g., laryngoscopy)
- Adverse effects of imaging (radiation, contrast adverse reactions, anxiety, claustrophobia)
- Adverse effects of anesthesia
- Dental injury
- Cranial nerve injury
- Rare complications of endoscopy (bleeding, infection, perforation, airway obstruction)

For harms associated with specific interventions considered in the guideline, see the "Major Recommendations" field.

Contraindications

Contraindications

- Regardless of whether computed tomography (CT) or magnetic resonance imaging (MRI) is performed, intravenous contrast should always be used, unless there is a contraindication, such as contrast allergy, renal insufficiency, or prior diagnosis that excludes the use of contrast.

- Vascular lesions and carotid body tumors are sometimes listed as contraindications to neck aspiration, but reports exist describing uncomplicated aspiration of such lesions; however, imaging is recommended prior to fine-needle aspiration (FNA) for any suspected vascular lesion (e.g., pulsatile or thrill on palpation; bruit on auscultation). Use of anticoagulation therapy does not result in increased risk of bleeding after neck fine-needle aspiration (FNA) and therefore is also not considered an absolute contraindication to FNA.

Qualifying Statements

Qualifying Statements

- The clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in evaluating neck masses. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible clinician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care, or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.
- Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent practice variation is expected for a strong recommendation than what might be expected with a recommendation. Options offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.
- Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the guideline development group (GDG) sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the panel was to be transparent and explicit about how values were applied and to document the process.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Considerations

The clinical practice guideline is published as a supplement to *Otolaryngology–Head and Neck Surgery*, which will facilitate reference and distribution. A full-text version of the guideline will be accessible, free of charge, at http://www.entnet.org . The guideline will be presented to the Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF). members as a miniseminar at the 2017 AAO-HNSF Annual Meeting & OTO Experience. Existing brochures and publication by the AAO-HNSF will be updated to reflect the guideline's recommendations. As a supplement to clinicians, an algorithm of the guideline's action statements has been provided (see Figure 1 in the original guideline

document). The algorithm allows for a more rapid understanding of the guideline's logic and the sequence of the action statements. The guideline development group (GDG) hopes that the algorithm can be adopted as a quick reference guide to support the implementation of the guideline's recommendations.

Implementation Tools

Clinical Algorithm

Foreign Language Translations

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

Pynnonen MA, Gillespie MB, Roman B, Rosenfeld RM, Tunkel DE, Bontempo L, Brook I, Chick DA, Colandrea M, Finestone SA, Fowler JC, Griffith CC, Henson Z, Levine C, Mehta V, Salama A, Scharpf J, Shatzkes DR, Stern WB, Youngerman JS, Corrigan MD. Clinical practice guideline: evaluation of the neck mass in adults. Otolaryngol Head Neck Surg. 2017 Sep;157(2_suppl):S1-S30. [117 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Sep

Guideline Developer(s)

American Academy of Otolaryngology - Head and Neck Surgery Foundation - Medical Specialty Society

Source(s) of Funding

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF).

Guideline Committee

American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) Guideline Development Panel

Composition of Group That Authored the Guideline

Panel Members: Melissa A. Pynnonen, MD, MSc, University of Michigan, Ann Arbor, Michigan, USA; M. Boyd Gillespie, MD, MSc, University of Tennessee Health Science Center, Memphis, Tennessee, USA; Benjamin Roman, MD, MSHP, Memorial Sloan Kettering Cancer Center, New York, New York, USA; Richard M. Rosenfeld, MD, MPH, SUNY Downstate Medical Center, Long Island College Hospital, New York, New York, USA; David E. Tunkel, MD, Johns Hopkins Medicine, Baltimore, Maryland, USA; Laura Bontempo, MD, MEd, University of Maryland School of Medicine, Baltimore, Maryland, USA; Itzhak Brook, MD, MSc, Georgetown University, Washington DC, USA; Davoren Ann Chick, MD, Maria Colandrea, DNP, Veterans Affairs Medical Center, Durham, North Carolina, USA, and Duke University School of Nursing, Durham, North Carolina, USA; Sandra A. Finestone, PsyD, Consumers United for Evidence-Based Healthcare, Baltimore, Maryland, USA; Jason C. Fowler, PA-C, Gannon University, Erie, Pennsylvania, USA; Christopher C. Griffith, MD, PhD, Emory University, Atlanta, Georgia, USA; Zeb Henson, MD, University of Mississippi Medical Center, Jackson, Mississippi, USA; Corinna Levine, MD, MPH, University of Miami, Miami, Florida, USA; Vikas Mehta, MD, MPH, Louisiana State University, Shreveport, Louisiana, USA; Andrew Salama, DDS, MD, Boston University, Boston, Massachusetts, USA; Joseph Scharpf, MD, Cleveland Clinic, Cleveland, Ohio, USA; Deborah R. Shatzkes, MD, Hofstra Northwell School of Medicine, Lenox Hill Hospital, New York, New York, USA; Wendy B. Stern, MD, Southcoast Hospital, North Dartmouth, Massachusetts, USA; Jay S. Youngerman, MD, Long Island ENT Associates PC, New York, New York, USA; Maureen D. Corrigan, American Academy of Otolaryngology—Head and Neck Surgery Foundation, Alexandria, Virginia, USA

Financial Disclosures/Conflicts of Interest

Financial Disclosure and Conflicts of Interest

Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call and were updated at each subsequent call and in-person meeting. After review and discussion of these disclosures, the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.

Disclosures

Competing Interests: M. Boyd Gillespie—research funding from ImThera, Inspire, and Olympus; consultant and new device development for Medtronic and Omniguide; Maureen D. Corrigan—salaried employee of American Academy of Otolaryngology—Head and Neck Surgery Foundation

Guideline Endorser(s)

American Academy of Emergency Medicine - Medical Specialty Society

American Academy of Physician Assistants - Professional Association

American Association of Oral and Maxillofacial Surgeons - Medical Specialty Society

American College of Radiology - Medical Specialty Society

American Head and Neck Society - Professional Association

American Society for Clinical Pathology - Professional Association

Head and Neck Cancer Alliance - Nonprofit Organization

Society of Otorhinolaryngology and Head and Neck Nurses - Medical Specialty Society

Triological Society - Medical Specialty Society

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the SAGE Journals Web site.

Availability of Companion Documents

The following are available:

Pynnonen MA, Gillespie MB, Roman B, Rosenfeld RM, Tunkel DE, Bontempo L, Brook I, Chick DA, Colandrea M, Finestone SA, Fowler JC, Griffith CC, Henson Z, Levine C, Mehta V, Salama A, Scharpf J, Shatzkes DR, Stern WB, Youngerman JS, Corrigan MD. Clinical practice guideline: evaluation of the neck mass in adults. Executive summary. Otolaryngol Head Neck Surg. 2017 Sep;157(3):355-71. Available from the SAGE Journals Web site.

Clinical practice guideline: evaluation of the neck mass in adults. Podcast part 1 and 2. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF); 2017 Sep. Available from the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Web site.

Clinical practice guideline: evaluation of the neck mass in adults. Pocket guide and mobile app. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF); 2017 Sep. Available from the AAO-HNSF Web site.

Rosenfeld RM, Shiffman RN, Robertson P. Clinical practice guideline development manual, third edition: a quality-driven approach for translating evidence into action. Otolaryngol Head Neck Surg. 2013 Jan;148(Suppl 1):S1-55. Available from the SAGE Journals Web site.

Patient Resources

The following is available:

Pynnonen MA, Colandrea M, Finestone SA, O'Connor SS. Plain language summary: evaluation of the neck mass in adults. Otolaryngol Head Neck Surg. 2017 Sep;157(3):372-82. Available from the SAGE Journals Web site .

Patient handouts with frequently asked questions are available in English and Spanish from the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on January 3, 2018. The information was not verified by the guideline developer.

This NEATS assessment was completed by ECRI Institute on November 29, 2017. The guideline developer did not acknowledge or provide confirmation for this NEATS assessment.

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